

5/05808

patient labeling for the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis. Use of the preclinical section of the FDA guidance documents can control the risks to health of adverse tissue reaction, infection, pain and/or loss of function, and revision by having manufacturers use surgical quality implant materials, adequately test and sterilize their devices, and provide adequate directions for use (and patient information).

To receive a guidance via fax machine, telephone Center for Devices and Radiological Health's (CDRH) CDRH Facts-on-Demand system at 800-399-0381, or 301-827-0111 from a touch-tone telephone. At the first voice prompt, press 1 to access the Division of Small Manufacturers Assistance Fax, at the second voice prompt, press 2, and then enter the document number followed by the pound sign (#). Then follow the remaining voice prompts to complete your request. The guidances are also available from the CDRH world wide web address at "http://www.fda.gov/cdrh".

#### IX. FDA's Tentative Findings

FDA believes that the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis should be reclassified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

#### X. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday:

1. Petition for Reclassification of Orthopaedic Shoulder Prostheses submitted by the Orthopedic Surgical Manufacturers Association, Warsaw, IN, received July 23, 1997.
2. Transcript of the Orthopedic and Rehabilitation Devices Panel Meeting, January 12 and 13, 1998, vol. I, pp. 12 to 114.

#### XI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### XII. Analysis of Impacts

FDA has examined the impacts of the notice under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages, distributive impacts and equity). The agency believes that this reclassification action is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the reclassification action is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this reclassification action, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

#### XIII. Request for Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this

document. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday.

Dated: May 17, 1999.

Linda S. Kahan,

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 99-13470 Filed 5-27-99; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket Nos. 98E-0485 and 98E-0850]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; Therma Choice™ Uterine Balloon Therapy System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Therma Choice™ Uterine Balloon Therapy System and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices,

the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Therma Choice™ Uterine Ballon Therapy System. Therma Choice™ Uterine Ballon Therapy System is indicated for use as a thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for Therma Choice™ Uterine Ballon Therapy System (U.S. Patent Nos. 5,105,808 and 4,949,718) from Gynelab Products, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated December 17, 1998, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Therma Choice™ Uterine Ballon Therapy System represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Therma Choice™ Uterine Ballon Therapy System is 1,031 days. Of this time, 852 days occurred during the testing phase of the regulatory review period, while 179 days occurred during the approval phase. These periods of time were derived from the following dates:

*1. The date a clinical investigation involving this device was begun:* February 17, 1995. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C.

360j(g)) for human tests to begin became effective on November 30, 1994. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on February 17, 1995, which represents the IDE effective date.

*2. The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e):* June 17, 1997. The applicant claims June 16, 1997, as the date the premarket approval application (PMA) for Therma Choice™ Uterine Ballon Therapy System (PMA P970021) was initially submitted. However, FDA records indicate that PMA P970021 was submitted on June 17, 1997.

*3. The date the application was approved:* December 12, 1997. FDA has verified the applicant's claim that PMA P970021 was approved on December 12, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 446 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 27, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 24, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99-13671 Filed 5-27-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Active Pharmaceutical Ingredient Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration (FDA) in cooperation with the Association of Food and Drug Officials (AFDO) is announcing the following workshop: Active Pharmaceutical Ingredient Workshop. The workshop will address issues related to the manufacture and control of active pharmaceutical ingredients.

**Date and Time:** The workshop will be held on June 5, 1999, from 8 a.m. to 5 p.m. Send information regarding registration by May 27, 1999.

**Location:** The workshop will be held at the Adam's Mark—Riverwalk, 111 Pecan St. East, San Antonio, TX 78205, 210-354-280 or 800-444-2326. Send information regarding registration by June 1, 1999.

**Contact:** AFDO, P.O. Box 3425 York, PA 17402, 717-757-2888, FAX 717-755-8089, e-mail "afdo@blazenet.net" or see the internet address "http://www.foodsafety.org/afdo" for more information.

**Registration:** Send registration information (including name, title, firm name, address, telephone, and fax number) along with registration fee payable to AFDO (address above). The registration fee will be \$199 for an AFDO member, \$249 for a nonmember, and \$449 for both workshop and AFDO conference. AFDO is charging these fees to cover its cost associated with the workshop and conference.

If you need special accommodations due to a disability, please contact AFDO at least 7 days in advance.

Dated: May 24, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99-13559 Filed 5-27-99; 8:45 am]

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